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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,145	01/07/2000	HIROSHI MIYAKE	0018-1086-PC	1855

22850 7590 01/22/2003

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/446,145

Applicant(s)
Hiroshi Miyake et al

Examiner
SUDHAKER PATEL, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 26, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-949) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 12/26/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09446145 is acceptable and a CPA has been established. An action on the CPA follows.

2. Restriction/Election:

Applicants had elected invention of Group I, claims (in part) 1-6,8 and species of Example compound 73-2 as recited on page 151 of the specification(= (2R)-1-(3,5-

BIS(trifluoromethyl)benzoyl)-4-(4-(S)-3-ethylmorpholino)-2-butynyl)-2-((1H-indol-3-yl)methyl)piperazine dihydrochloride). Accordingly, this application will be examined bearing in mind the subject matter of invention consisting of species as elected by the applicants only.

The elected species represents following variables in the generic Formula of claim 1:

R1 = Phenyl with 3,5-trifluoromethyl;

Y = Alkylene;

R2 = indoyl;

R3 = alkyl;

R4 = morphonyl(lower)alkyl.

Applicants are reminded of the election of species guidelines provided in MPEP 803.02, which are followed for examination. Portion of MPEP is provided for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be taken. On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or

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rendered obvious by the prior art, the amended Markush-type claim will be reexamined.

The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The elected species was not found in the prior art. When the search was expanded to species with :

R1 = Phenyl with 3,5-trifluoromethyl;

Y = Alkylene;

R2 = indoyl;

R3 = alkyl;

R4 = Pyridyl(lower)alkyl-amino, an art was found.

As per the guide lines above, the examination was limited to compounds of formula as shown in generic claim 1 wherein R1 = Phenyl with 3,5-trifluoromethyl;

Y = Alkylene;

R2 = indoyl;

R3 = alkyl;

R4 = Pyridyl(lower)alkyl-amino; indoyl type heterocycle ring only. All other definitions of R1 = aryl which may have substituents; Pyridyl; thiazolyl; imidazolyl or pyrazolyl; piperidyl;

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homomorpholinylamino; thiomorpholinoamino and others; R2 = aryl which may have substituents; R3 = H; R4 = other than morpholino(lower)alkyl; Pyridin-lower alkyl-amino, and also all other definitions of the other variables from the generic claims are held withdrawn from consideration.

The restriction/election is considered proper, and has been made **FINAL**.

2. ***Priority***

Receipt is acknowledged of papers filed on 1/7/2000 purporting to comply with the requirements of 35 U.S.C. 119(a)-(d) and they have been placed of record in the file. Attention is directed to the fact that the original claims of as presented in the priority document, i.e. Australia PO7359 dated 6/17/1997 have been amended to a great extent and the same are presented in the instant application which is a 371 of PCT/JP98/02613 dated 6/15/1998.

Therefore, the priority date for this application would be considered as 6/15/1998. And not 6/17/1997.

3. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,,45,6,8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,5,8,9 of Application No.09091269 filed 12/12/1996, now U.S.P. 6087357. Although the conflicting claims are not identical, they are not patentably distinct from each other because compounds of instant claims 1-4, process claim 5, composition claim 6 and method of use claim 8 are claiming identical subject matter e.g. in Formula of generic claim 1 the variables R1 = aryl; Y = bond or lower alkylene; R2 = aryl or indoyl; R3 = H or lower alkyl; R4 = morpholinyl(lower alkyl; homomorphonyl; morphonyl(loweralkynyl; morphonylamino(lower)alkyl are identical to what has been claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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4. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3,5-6,8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.P 6087357 filed as U.S. Sr. # 09091269 which is a 371 of PCT/JP 96/03641 filed 6/15/1998 and WO 9722597 filed 12/12/1996 and published on 6/26/1997.

Claim Rejections - 35 U.S.C. § 112

2.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-6,8 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

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- (A). Evidence that claim(s) fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Priority Document Australia PO7359 6/17/1997. In that paper, applicant has stated claim1 in a different manner, and this statement indicates that the invention is different from what is defined in the claim(s) because claim1 and dependent claims 2-6,8 represent different subject matter as compared to original claims in the priority document cited earlier..
- (B). In claim 1 R1 and R2 represent “aryl” which is indefinite and not acceptable. See In re Sus et al, 135 USPQ 301; In re Lund et al, 153 USPQ 625.
- (C). In claim 1 the variables R1 and R2 are presented as:”substituted aryl”. This is indefinite and not acceptable. See In re Sus et al, 134 USPQ 301.
- (D). Claim 1 as presented recites different subject matter as compared to claim 1 of the priority document. This will constitute new matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr.Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

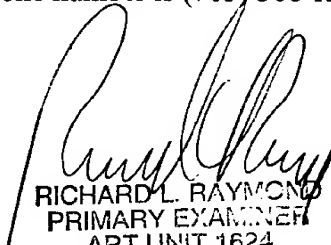
A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

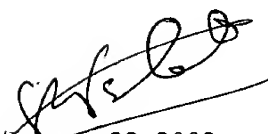
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Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.


RICHARD L. RAYMOND
PRIMARY EXAMINER
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Sp/January 22, 2003.